UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S
MEMORANDUM IN OPPOSITION TO THE UNITED STATES' MOTION FOR PARTIAL SUMMARY JUDGMENT, AND
REPLY IN SUPPORT OF ABBOTT'S
MOTION FOR PARTIAL SUMMARY JUDGMENT

Dated: August 28, 2009

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TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

STATUTES AND LEGISLATIVE MATERIALS

RULES

TABLE OF AUTHORITIES
(continued)

Page

OTHER AUTHORITIES

INTRODUCTION

The Government moves for partial summary judgment as to several elements of its False Claims Act ("FCA") claims relating to Medicaid (not Medicare) and certain of Abbott's affirmative defenses. As shown below and in defendants' common brief, however, the only conceivable summary judgment would be in favor of *Abbott*, not the Government.[1] The record in this case shows that CMS and the state Medicaid programs knew the actual market prices for Abbott's four subject drugs, yet they intentionally chose to pay healthcare providers for those and other products based on the higher compendia AWPs. At a minimum, this record raises genuine issues of material fact that preclude judgment for the Government.

Abbott also sets forth below the reply in support of its own limited motion for summary judgment, which exposes certain key legal defects in the Government's case, particularly relating to damages and the statute of limitations. Based upon the controlling law and the detailed factual record amassed by the parties, Abbott's motion for partial summary judgment should be granted, and the Government's counter-motion denied.

STATEMENT OF FACTS

A. Abbott's Former Hospital Products Division And The Subject Drugs.

The Subject Drugs at issue in this matter are vancomycin (an antibiotic), dextrose, saline, and sterile water (three solutions used in a variety of IV infusion treatments). These multiple-source generic products are very different than the drugs this Court has seen in past cases. The products are generally administered via an infusion pump or IV injection, and require much more labor than traditional pharmacy pill dispensing: the products must be mixed in a sterile environment per physician's orders, must often be refrigerated and transported directly to a

[1] *See Combined Memorandum Of Defendants Abbott Laboratories, Inc., Dey, Inc., And Boehringer Ingelheim, Corp. In Opposition To The United States' Cross-Motions For Partial Summary Judgment* ("C. Br."), filed contemporaneously.

patient's home, and are dispensed through the use of ancillary supplies (such as bags, tubes, and pumps), often with a nurse's assistance. (AF ¶¶ 1-3.)[2]

Throughout the claims period of 1991-2001, these products were sold by Abbott's former Hospital Product Division ("HPD"). (*Id.* ¶ 4.) HPD had two business units that sold the Subject Drugs: the Hospital Business Sector ("HBS") and the Alternate Site Business Sector ("Alternate Site"), each with its own contracting department, sales force, and support staffs. (*Id.* ¶¶ 5-6.) HBS marketed its products directly to hospital purchasing departments, and accounted for approximately 90% of all HPD revenues. (*Id.* ¶ 7.) Importantly, HBS's hospital customers were not generally reimbursed based on compendia prices such as AWP. (*Id.* ¶ 8.) Plaintiffs' claims do not relate to HBS sales.

Alternate Site serviced medical providers in non-hospital settings, such as clinics and dialysis centers, and was divided into three business groups: Renal, Alternate Site Product Sales, and Home Infusion Services. (*Id.* ¶¶ 9-10.) The Renal group was responsible for about 50% of Alternate Site revenues. (*Id.* ¶ 11.) Like HBS, Renal's customers were generally not reimbursed by reference to compendia prices, and thus that group is not part of plaintiffs' claims. (*Id.* ¶ 12.) Plaintiffs instead focus on Alternate Site Product Sales and Home Infusion Services, which together accounted for only about 5% of total HPD revenues. (*Id.* ¶ 13.)

Alternate Site Product Sales concentrated on sales of HPD products to non-hospital providers, both individually and through group purchasing organizations ("GPOs"). (*Id.* ¶ 14.) Home Infusion Services, a small group with fewer than 40 customers, was not sales-oriented.

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[2] Citations to *Abbott Laboratories Inc.'s Rule 56.1 Statement Of Additional Facts That Preclude Summary Judgment In Favor Of The Government*, filed herewith, are noted (AF ¶__.). Citations to Defendants' combined 56.1 statement, filed herewith, are noted (CF ¶ __.). Citations to Abbott's original Rule 56.1 statement (Dkt. No. 6187) are noted (SOF ¶__.). Citations to Abbott's response, filed herewith, to the United States' Rule 56.1 statement as to Abbott (Dkt. No. 6321) are noted (SOF Resp. ¶ __.) Citations to the Government's summary judgment brief common to all defendants (Dkt. No. 6317) are noted ("G. Def. Br."), and to the Government's summary judgment brief as to Abbott only (Dkt. No. 6319) as ("G. Abt. Br.").

Instead, it offered a variety of services – including business counseling, training, inventory management, and help with claims submissions – to providers interested in starting up home infusion clinics. (*Id.* ¶¶ 15-16.) In exchange, Abbott was paid either at a per diem rate, or based upon a percentage of the amounts collected from third party payors. (*Id.* ¶ 19.) In addition, Abbott owned three home infusion pharmacies, which were shut down between 1996 and 2001. (*Id.* ¶¶ 20-21.) In 1998, Abbott decided to discontinue all Home Infusion Services operations, and it was phased out gradually until finally closing in 2001. (*Id.* ¶¶ 22-25.)

B. Abbott Priced The Subject Drugs Without Any Intention To Influence Medicare Or Medicaid Payment Levels.

1. HBS (Not Alternate Site) Set List Prices For The Subject Drugs.

Like other pharmaceutical manufacturers, Abbott had different price levels for different types of customers. (*Id.* ¶ 26.) The lowest (best) price for the Subject Drugs was made available to the Government, and Abbott sold the Subject Drugs at this low price (far below the compendia AWP) to agencies like the Veteran's Administration and the Department of Defense. (*Id.* ¶ 27.) At the other end of the spectrum was the List Price, also referred to as the Catalog or Direct Price, which was the highest price available in the marketplace. (*Id.* ¶¶ 28-30.)

List Price was the price available to customers who did not have a negotiated contract with Abbott. (*Id.* ¶ 31.) Because most of Abbott's sales of the Subject Drugs were made through negotiated contracts, there were relatively few sales at List Price. (*Id.* ¶ 32.) List Price sales, though not common, were valuable to Abbott, since they comprised the highest profit margin of any sales. (*Id.* ¶ 33.) These sales sometimes occurred in situations where a competitor has a supply shortage, allowing Abbott to make sales at the high List Price to the competitor's customers as they sought to cover the shortage. (*Id.* ¶ 34.) List Price also was useful to Abbott because it encouraged customers to enter into negotiated product contracts. (*Id.* ¶ 35.)

List Prices for the Subject Drugs were set by HBS (whose customers, the hospitals, were not reimbursed based on AWP, as discussed above). (*Id.* ¶¶ 8, 37.) Alternate Site had no role in this process. (*Id.* ¶ 38.) List Prices were not set by reference to, or in order to influence, the AWPs for the Subject Drugs. (*Id.* ¶ 39.) From 1991-1999, List Prices for the Subject Drugs were adjusted approximately annually to reflect changes in the Consumer Pricing Index. (*Id.* ¶ 40.) This annual adjustment typically resulted in an increase of about 3-5%. (*Id.* ¶ 41.)

2. HBS (Not Alternate Site) Reported Prices To The Compendia.

Alternate Site also had no role in reporting prices to the various publishing compendia. HBS handled that task. (*Id.* ¶¶ 42-43.) During the time in question, HBS accurately reported to the compendia Abbott's List (Direct) Price and its published WAC for the Subject Drugs. (*Id.* ¶ 44.) Unlike other cases this Court has reviewed, Abbott did not provide to the compendia an AWP or a "suggested" AWP for the Subject Drugs. (*Id.* ¶ 45-46.) HBS reported List Price and WAC to the compendia because that is what they believed was requested. (*Id.* ¶ 47.) Throughout all of these years, none of the compendia gave any contrary instruction, requested any alternative pricing, or indicated to Abbott in any way that they expected Abbott to report the negotiated, confidential prices paid by Abbott's contract customers. To the contrary, when Abbott specifically inquired of First Data Bank ("FDB") about this issue, its representative Kaye Morgan (who was responsible for the pricing information that FDB published) stated that FDB expected Abbott to report its highest, undiscounted price. (*Id.* ¶ 48.) That is List Price, and that is what Abbott reported. Before working at FDB, Ms. Morgan was employed by Abbott from 1975-1999, was familiar with Abbott's pricing, and certainly understood that Abbott's List Price was higher than the average transactional price for Abbott's products. (*Id.* ¶¶ 49-50.)

C. Abbott Did Not Market The Spread.

The way Abbott marketed the Subject Drugs is significant. Rather than focusing on

individual products, Alternate Site Product Sales field representatives marketed the entire HPD product portfolio as a package. (*Id.* ¶ 64.) The sales representatives were trained to market based upon the breadth of the product portfolio, quality, reliability of supply, customer service, and competitive price. (*Id.* ¶ 65.) Importantly, sales representatives were *not* instructed to market based upon any "spread" between the customer's acquisition cost and the amount the customer would receive from Medicare or Medicaid. (*Id.* ¶ 66.) To the contrary, many former sales representatives testified that they understood it was Abbott's practice not to market the spread. (*Id.* ¶ 67.) Numerous others testified that the issues of AWP and spread were not at all relevant to their work, and that they did not discuss those issues with their customers. (*Id.* ¶ 68.)

D. When Abbott Discovered The Inadvertent Disparity Between Its List Prices And Its Contract Prices, It Took Steps To Reduce That Disparity.

Throughout the 1990s, as a result of increased competition in the marketplace and other factors, sales at prices set by contract with particular customers accounted for a substantial and growing portion of HPD's business. (*Id.* ¶ 69.) Over these years, contract prices for HPD generic products generally decreased due to market forces, particularly as more generics flooded the marketplace and customers banded together into large GPOs, increasing their bargaining power. (*Id.* ¶ 71.) This fierce competition resulted in a gradual widening of the difference between negotiated contract prices and List Prices (which steadily increased due to the routine, CPI-based price adjustments made by HBS, as described above). (*Id.* ¶¶ 40, 72.)

The Government has long known about the difference between pharmaceutical companies' published list prices and the compendia AWPs, on the one hand, and the lower prices that the companies negotiated with customers, on the other. (C. Br. at 11-20.) Public discourse about this issue significantly intensified by 2000, as Congress considered various legislative initiatives that would have changed Medicare and Medicaid reimbursement to discontinue any

reference to compendia-published prices. (C. Br. at 19-20.) At every turn, Congress elected to maintain the compendia-based system – going so far as to enact legislation in 2000 specifically barring HCFA/CMS from "directly or indirectly decreas[ing] the rates of reimbursement" for drugs covered by Medicare Part B. *See* Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, app. F, 114 Stat. 2763, 2763A-524.

In light of the increasing attention to this issue, beginning in or about late 2000, Abbott undertook a review of pricing practices within HPD, and consequently discovered the difference that had gradually grown over the years between List Prices and negotiated contract prices for HPD products. (AF ¶ 73.) This disparity was unintentional, and was not designed by Abbott to influence Government payment levels under Medicare or Medicaid. (*Id.* ¶ 74.) As part of this internal review, Abbott considered many factors, including its own business, the industry generally, and the overall discourse in Congress and elsewhere about pharmaceutical issues. (*Id.* ¶ 75.) Viewing the totality of the circumstances, a decision was made to reduce the List Prices for certain HPD products. (*Id.* ¶ 76.) This reduction, effective in or about May 2001, decreased the unintended disparity between List Prices and negotiated contract prices. (*Id.* ¶ 77.)

ARGUMENT

I. GENUINE ISSUES OF MATERIAL FACT REQUIRE DENIAL OF THE UNITED STATES' MOTION FOR SUMMARY JUDGMENT.

Summary judgment against a party (like Abbott) that does not bear the burden of proof is appropriate only where the record shows that "'there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)). If, after viewing the evidence "in the light most favorable to the non-moving party," the Court concludes

that that a reasonable jury could find in favor of that party, then summary judgment must be denied. *Id.* at 36; *Sanchez v. Alvarado*, 101 F.3d 223, 227 (1st Cir. 1996).

A. Genuine Issues Of Material Fact Preclude Summary Judgment On Scienter.

To impose FCA liability, plaintiffs must prove that Abbott "knowingly or recklessly cheated the government." *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 232 (5th Cir. 2008); *see also* 31 U.S.C. § 3729(b). Mistakes, negligence, or even "[taking] advantage of a disputed legal issue" are not enough. *See Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478-79 (9th Cir. 1996); *see also Hindo v. Univ. of Health Scis. / Chi. Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995) ("'The requisite intent is the knowing presentation of what is known to be false.' In short, the claim must be a lie.") (citation omitted). Not surprisingly, courts (including this one) have overwhelmingly recognized that this "scienter" inquiry is highly fact-intensive and therefore is not ordinarily amenable to summary judgment. *See, e.g.*, *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 154 (D. Mass. 2008); *see also United States ex rel. Koch v. Koch Indus., Inc.*, 57 F. Supp. 2d 1122, 1130 (N.D. Okla. 1999) ("[T]he 'knowingly' prong of the FCA is one of fact, and should be decided by the finder of fact at trial and not prematurely decided on summary judgment."). This case is no exception.

1. AWP Was And Remains Undefined, And Abbott Certainly Did Not Understand It To Mean An Actual Average Market Price.

Where a defendant acts pursuant to a reading of an ambiguous statute, contract, or regulation that is not "objectively unreasonable," scienter cannot be shown. *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 & n.20 (2007). Here, there did not exist at any time during the claims period (and there does not exist even today) a statute, regulation, or guidance of any sort purporting to define AWP as an actual average market price. (C. Br. at 24-29.) Indeed, this Court's own independent expert recognized that "inconsistent and ambiguous information exists

even currently concerning what type of price AWP measures." *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 460 F. Supp. 2d 277, 285 (D. Mass. 2006). Given the admitted ambiguity regarding AWP, Abbott cannot be found, as a matter of law, to have *lied* in reporting its List Prices for the Subject Drugs to the publishing compendia. *Hindo*, 65 F.3d at 613.

(a) Abbott Did Not Understand The Compendia AWPs To Represent Actual Average Market Prices, And It Reported Accurate Prices To The Compendia In Good Faith.

First, the Government cannot point to any evidence establishing that Abbott believed AWP was supposed to represent an actual average market price, or that Abbott understood it was reporting prices to the compendia incorrectly. AWP was not a price set by Abbott, reported by Abbott, published by Abbott, or charged by Abbott to any of its customers. (AF ¶¶ 53-55.) Not surprisingly, then, there was no uniform understanding of AWP within Abbott. (*Id.* ¶ 52.) Those few who actually understood the details of AWP knew that it was set by the compendia as a markup over Abbott's List Price. (*Id.* ¶ 57.) The vast majority of those current and former Abbott HPD personnel deposed, however, either knew nothing at all about AWP except that it stood for "average wholesale price," or knew only that it was published in the compendia and had some relationship to Abbott's prices. (*Id.* ¶¶ 58-59.) Critically, *no one* with any comprehension of the term understood it to mean an actual average market price. (*Id.* ¶ 51.)[3] The most that can be said, based on the record, is that Abbott understood AWP for products like the Subject Drugs to reflect a benchmark price calculated by the compendia as a markup over Abbott's List Price. (*Id.* ¶ 61.)

And Abbott certainly did not understand that it was supposed to be reporting discounted,

[3] One witness testified that at one time he assumed AWP was a literal average price, but as he learned more about it later, he discovered that it was merely a benchmark, undiscounted price. (*Id.* ¶ 60.) This is perfectly consistent with the understanding of various federal and state officials, who understood AWP as an undiscounted benchmark price. (*See, e.g.*, C. Br. at 3, 8-9.)

contract prices for its generic products to the compendia. Abbott reported its List Prices because that is what it believed was being requested, and none of the compendia ever suggested that this was wrong. (*Id.* ¶ 47.) Indeed, when Abbott asked FDB what price should be reported, FDB told Abbott to report its highest, undiscounted price. (*Id.* ¶ 48.) Acting in good faith in accordance with these instructions – especially in light of the utter lack of contrary statutory or regulatory guidance – cannot be considered "objectively unreasonable," much less knowing or reckless misconduct. *See Mylan*, 608 F. Supp. 2d at 154-55; *United States ex rel. K & R Ltd. P'ship v. Mass.Hous. Fin. Agency*, 530 F.3d 980, 984 (D.C. Cir. 2008) ("At bottom, K & R and MassHousing simply disagree about how to interpret ambiguous contract language. Given that and K & R's inability to point to anything 'that might have warned [MassHousing] away from the view it took,' there is no genuine issue as to whether MassHousing knowingly presented false claims to HUD." (*quoting Safeco*, 551 U.S. at 70)); *United States ex rel. Kersulis v. RehabCare Group, Inc.*, No. 4:00-CV-00636GTE, 2007 WL 294122, at *17 (E.D. Ark. Jan. 29, 2007) (summary judgment in favor of defendants as to scienter was appropriate where "it [was] undisputed that prior to 2002, HCFA/CMS never issued formal guidance to either the provider community or to the fiscal intermediaries").

The Government tries to overcome this issue by claiming that "Abbott had an obligation to familiarize itself with the legal requirements, standards and procedures of the Medicaid program," which – according to the Government – should have told Abbott that reporting List Prices to the compendia (despite FDB's instructions) was wrong. (G. Abt. Br. at 19.) Not so. The state Medicaid programs candidly acknowledged that they understood AWP to be a compendia price that was entirely divorced from (and far higher than) the average market price. (C. Br. at 8-11.) The programs chose to pay providers based on this high price benchmark in

order to make up for the inadequate fees paid for medical services and supplies, and otherwise to ensure that Medicaid patients had equal access to care. (*Id.*) This was especially true in the context of payments for labor-intensive products, like the Subject Drugs, that were utilized in home infusion therapy. (*See* Part I.B.3, *infra*.) Nothing about the way the Medicaid programs employed AWP suggests that Abbott committed knowing or reckless misconduct.

Similarly, the Government's discussion of Abbott's supposed business practices merely serves to underscore the disputed factual issues that surround scienter. (G. Abt. Br. at 20-24.) For example, the Government makes much of the fact that Abbott was involved in the home infusion therapy business through its ownership of three pharmacies and its operation of the small Home Infusion Services unit. Yet these business activities in no way suggest that Abbott knowingly or recklessly made false statements to the Government about its prices for the Subject Drugs. Home Infusion Services, which operated Abbott's three home infusion pharmacies and also provided a variety of services to a small group of customers, had no role in setting List Prices or in reporting prices to the compendia. (AF ¶¶ 10, 16, 20, 38, 43.) HBS did those things, and it did so without regard to any impact on Government payments or the Alternate Site business (of which Home Infusion Services was a small part). (*Id.* ¶¶ 37, 39, 42, 47.) Moreover, the notion that Abbott was manipulating its prices (thereby knowingly exposing itself to massive liability) in order to prop up this tiny business unit is not only illogical on its face, but belied by the record as well. Home Infusion Services was always very small (fewer than 40 customers), it was outside Abbott's core business, and it was marginally profitable at best. (*Id.* ¶¶ 15, 23.) Because of these issues, Abbott decided in 1998 to close Home Infusion Services (*id.* ¶ 22) – not the actions of a company bent on using this business to reap windfall profits at the expense of Medicare and Medicaid, as the Government suggests.

The Government also tries to use the mere existence of spreads on the Subject Drugs to establish scienter. (G. Abt. Br. at 23-24.) This Court rejected such an argument in *Mylan*, and the result should be no different here. *Mylan*, 608 F. Supp. 2d at 137-38, 153-55 (denying summary judgment on scienter even though defendant's products had so-called "megaspreads").[4] The record here shows that the spreads for these products grew over time as a result of two independent actions: (i) HBS (whose hospital customers were not paid based on AWP) made annual, CPI-based increases in the List Prices for HPD products, without input from or influence by Alternate Site, at the same time that (ii) market forces gradually drove negotiated contract prices within Alternate Site down. (AF ¶¶ 37-38, 41, 71.) The spread was not engineered by Abbott to manipulate AWP or to increase Government payments to providers. (*Id.* ¶¶ 64-68.) To the contrary, when Abbott undertook a review of its pricing and discovered the inadvertent disparity, it took corrective action and lowered the List Prices to reduce the spread. (*Id.* ¶¶ 73-77.) The Government argues that the spread was not inadvertent (G. Abt. Br. at 23), but, at summary judgment, Abbott is entitled to have all factual inferences weighed in its favor.[5] At best, the Government's various pot-shots merely underscore just how factually mired the issue of scienter is in this case.[6]

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[4] Moreover, as discussed below with respect to falsity, the size and import of the spread on the Subject Drugs is itself a disputed question of fact that precludes summary judgment. (*See* Part I.B.1 *infra*.)

[5] The Government's reliance on *United States ex rel. Longhi v. Lithium Power Techs.*, Nos. 08-20194, 08-20306, 2009 WL 1959259 (5th Cir. July 9, 2009), is misplaced. There, the Government established scienter through a collection of multiple false statements, which included "egregious[]" "lie[s]" and purposefully or recklessly misleading statements that defendants did not claim were inadvertent. *Id*. at *5, *10. In short, defendants "blatantly deceived" the Government. *Id*. at *11. The Court never suggested that inadvertence was irrelevant; to the contrary, it noted that the district court refused to consider any misstatements that "resulted from mere negligence." *Id*. at *3.

[6] For example, the Government refers to a situation in 1995 when the List Prices for a few NDCs of vancomycin were lowered and then, about a month later, raised back up. (G. Abt. Br. at 6, 21.) The Government claims that the prices were raised because of customer complaints regarding reimbursement (*id.*), but Abbott witnesses, including its corporate designee on this very topic, have disputed that notion and have testified instead that the prices were raised back up, among other reasons, because HBS's practice is to make List Price changes only as part of the traditional annual cycle, and the March 1995 changes were outside that practice. (AF ¶¶ 80-82.) This is a classic disputed issue of fact. The Government also makes passing reference to the Medicare Working Group at

(b) Others In The Industry, And The Government Itself, Viewed AWP As Abbott Did.

Second, it is undisputed that other manufacturers in the pharmaceutical industry shared Abbott's view of AWP as a benchmark price, and not a discounted market price. (*See* C. Br. at 32; *see also* individual briefs of defendants Dey and Roxane). This is completely consistent with the Government's own understanding of AWP. (*See* C. Br. at 11-21.) Even standing alone, this is enough to raise a genuine issue of fact surrounding whether Abbott's pricing and reporting practices were "knowingly" or "recklessly" false as a matter of law. *See United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998) ("A standard billing practice within an industry could hardly be said to be false, when no controlling authority requires parties to submit claims in nautical rather than statute miles.").

2. Abbott's Reporting Of AMP To The Government For The Subject Drugs Raises A Genuine Issue Of Material Fact As To Scienter.

The Government's argument is premised on the idea that Abbott submitted false prices for the Subject Drugs to the compendia, while at the same time hiding its true prices from the Government. The record shows otherwise. As discussed above, AWP was never defined at all, and certainly was not defined as an average price net of discounts, rebates, and chargebacks. There was another pricing metric that *was* so defined, however – Average Manufacturers Price ("AMP"). *See* 42 U.S.C. § 1396r-8(k)(1). This alone is enough to preclude summary judgment

(continued…)

Abbott, suggesting that this group "used its status to participate as an industry leader on certain initiatives, including legislative initiatives." (G. Abt. Br. at 22.) This bald statement has no apparent bearing on scienter and is in any event untrue. Members of the Medicare Working Group – a short-lived assemblage of persons within the company who reviewed various pending legislative initiatives relating to Medicare and Medicaid – testified that this was merely a study group that never took any action on anything. (AF ¶¶ 81-82.) There is no evidence in the record (and the Government cites none) that this group had any role whatsoever in price setting or price reporting. Finally, the Government alludes to the 2001 criminal settlement involving TAP Pharmaceuticals. (G. Abt. Br. at 22.) The Court has consistently recognized that the TAP settlement is irrelevant to this case. (*See, e.g.*, 5/16/07 Transcript of Proceedings at 57-62.) It is certainly not the sort of admissible evidence the Court can consider at summary judgment.

on scienter, as it was surely not unreasonable for Abbott to interpret the undefined AWP as something different from AMP, which was specifically defined as a net, discounted price. (*See* C. Br. at 27.) Also, there is no dispute that, when the Government defined AMP and required that manufacturers submit AMP for all products to HCFA/CMS on a quarterly basis, Abbott complied. Indeed, over the course of the claims period, Abbott reported its AMP for the Subject Drugs – which was lower than the compendia AWP – directly to the Government about 40 times. (AF ¶¶ 27, 62-63.) At a minimum, this reporting of AMP raises a genuine issue of fact as to whether Abbott knowingly or recklessly made false statements to the Government by submitting its List Prices to third party publishing compendia.[7]

B. Genuine Issues Of Material Fact Preclude Summary Judgment On Falsity.

There is also a genuine issue of material fact regarding whether any false claim exists here. A claim cannot be "false" unless it objectively violates a defined "law, regulation, or other source." (C. Br. at 24.) There was no such legal guidance here with respect to AWP, and that by itself creates a triable issue as to falsity. In addition, summary judgment on falsity should be denied in this case because of the genuine factual disputes described below.

1. There Is A Genuine Issue Of Material Fact As To Whether Abbott's Statements Were False.

Fundamentally, there is a dispute over whether Abbott made false statements. The Government's FCA claim is based on the AWP for the Subject Drugs, but Abbott did not report an AWP to anyone for these products, much less to the Government. (AF ¶¶ 45, 54.) Abbott reported List Prices to third-party publishing compendia because, to the best of Abbott's

[7] The Government attempts to minimize the importance of AMP reporting, arguing that the manufacturers' insistence upon keeping AMP confidential prevented the Government from comparing that information to AWPs. (*See* Dkt. No. 6316 ¶¶ 97-115.) If that is truly the Government's view, then it cannot possibly claim that these same manufacturers understood that they had an obligation to make this same pricing information public by reporting it to the compendia. This too raises a question of fact on scienter.

knowledge (and pursuant to express instructions), that is what was being requested. (*Id.* ¶ 47.) There is no dispute that Abbott accurately reported its List Prices to the compendia. (*Id.* ¶ 44.)

Nor is there any colorable dispute that Abbott's List Prices were real prices actually available in the marketplace. (*Id.* ¶ 31.) The fact that Abbott made relatively few sales at List Price does not mean that the price was false; List Price sales were made, and Abbott reaped hefty profits from them. (*Id.* ¶¶ 32-33.) This is demonstrated forcefully by the experience of the relator in this case. In the early 1980s, Ven-A-Care's former President Luis Cobo, then-owner of a retail pharmacy, contacted Abbott to order a small quantity of saline. Because he did not have a contract, he was required to pay List Price and to purchase an entire case. (*Id.*)[8] For Ven-A-Care to now call that very List Price false is ironic, indeed.

Unable to attack Abbott's reported List Prices as false on their face, the Government instead urges the Court to find falsity simply based on the spread between those prices and the lower contract prices that were negotiated with customers. (G. Abt. Br. at 14-15.) The Court should refuse for two reasons. *First*, there is a genuine dispute over the Government's calculations of the spreads at issue, which are set forth in untimely (and therefore inadmissible) reports of new experts and are in any event based upon the flawed methodologies employed by the Government's damages expert, Dr. Duggan – whose testimony and opinions should be excluded on *Daubert* grounds. (*See, e.g.*, SOF Resp. ¶ 8; *see also* Dkt. No. 6177.) *Second*, even assuming that – as measured by percentages – the spreads on the Subject Drugs could be called "mega-spreads" as this Court has used the term, summary judgment would still be inappropriate.

[8] Cobo's experience is entirely consistent with the expectation of Dr. Bruce Vladeck, Administrator of CMS from 1992 to 1997. Vladeck believed that for multiple-source supplies such as saline solution, group purchasing organizations "achiev[ed] discounts of 98 and 99 percent" while "only the weakest and smallest scale buyers pay anything close to [List Price]." (SOF ¶ 52.) As a result, Dr. Vladeck "would not have been surprised" to learn that a small purchaser of saline solution paid a list price of $10 per bag while a contracted customer paid $1 per bag—an expected "spread" of 900%. (*Id.*) This pricing activity was likewise confirmed in a 1994 study conducted by Paul Chesser in the Office of the Inspector General, where his analysis showed typical discounts from AWP of "90 plus percent" for injectable solutions. (*Id.* ¶ 57.)

The Government itself has recognized that the proper way to evaluate drug spreads is in dollars, not percentages. (CF ¶¶ 76-77.) Viewed that way, it is undisputed that the spreads for the Subject Drugs are far less than spreads this Court has previously held to be *immune from liability*. As just one example, the Court ruled in the Track 1 trial that Johnson & Johnson was not liable despite the fact that the spreads on its Remicade® product were as high as $207 per unit. Even using the Government's grossly exaggerated calculations, the highest dollar spread at issue in this case (which applies to a single NDC of vancomycin) is only $72. (*See* Ormond Decl.) Moreover, the spreads for 38 of the 39 solution NDCs are all less than $16 (with many less than $5).[9] (*Id.*) If causing an overpayment of $207 was no basis for liability, how could the result be different here? At a minimum, this raises an issue of fact.

2. The Government Knew The Actual Market Prices Of The Subject Drugs.

(a) CMS Knew That The Actual Market Prices For Abbott's Solutions Were More Than 90% Below AWP.

Dr. Bruce Vladeck confirmed that CMS's "expectations yardstick" for solutions – like saline, dextrose, and sterile water – was that they could be purchased in the market at discounts of over 90% off of AWP (a 900% spread). (SOF ¶ 52.) This expectation was consistent with articles in the media (such as the 1996 "Hooked on Drugs" article in Barron's, which reported that *Abbott's* solution pricing was, "on average, 80%-93% below" AWP) and with the Government's own investigations. (CF ¶ 3(h).)

For instance, in 1994, the Office of Inspector General worked with Medicaid programs in eleven states to collect invoices from pharmacies, in order to compare market prices to the compendia AWPs. (SOF ¶ 58.) The Medicaid pharmacy directors urged OIG to "include non-

[9] According to the Government, the last NDC, a 2000 ml dextrose solution, has a spread of about $72. (*Id.*) Abbott disputes this figure, but even if it were correct, that is still far less than the J&J spreads at issue in Track 1.

traditional retail pharmacies such as hospitals, home IV, nursing homes, physicians, etc." because "[t]he State officials believed that these pharmacies purchased at substantially bigger discounts than traditional retail pharmacies." (*Id.*) As part of this study, OIG collected invoices for Abbott's sterile solution products showing pharmacy acquisition prices of more than 90% off of AWP, and it reported this information to HCFA/CMS. (*Id.* ¶ 57.)

(b) CMS Knew That The Actual Market Price For Abbott's Vancomycin Was More Than 75%-80% Below AWP.

Likewise, CMS's "expectations yardstick" for vancomycin was that it was available in the marketplace during the claims period at prices about 75% to 80% below the compendia AWP (spreads up to 400%). In 1991, HCFA commissioned OIG to conduct an invoice study of dialysis clinics, so that CMS would have actual market data to factor into its evaluation of then-pending proposals to change the Medicare drug payment levels. (SOF ¶ 54.) As part of its study, OIG collected invoices for Abbott's vancomycin (which is regularly used in dialysis) and compared the prices to compendia AWPs. The OIG documents showed that the clinics were purchasing vancomycin at discounts of about 80% off of AWP. (AF ¶ 83.) In 1992, OIG published the results of this investigation, and it pegged the average cost (or "Estimated Acquisition Cost") for vancomycin at $5.00 – about 75% below the median AWP. (SOF ¶ 54.)[10]

As to each of the Subject Drugs, it is therefore clear that the Government knew that the compendia AWPs were far higher than actual market prices. This is perfectly consistent with the Government studies and testimony showing that generic products generally were available for a fraction of the compendia AWPs. (*See, e.g.*, C. Br. at 2, 14.) The Government's detailed knowledge precludes summary judgment as to falsity.

[10] The expectations for vancomycin pricing reflected in the 1992 OIG report are repeated in public reports throughout the claims period. In June 1996, Barron's reported that Abbott's vancomycin was sold at 74% below AWP. (AF ¶ 87.) In December 1997, the OIG reported that GPO prices for vancomycin ranged from $2.02 to $6.99, while the AWP was about $10.07. (*Id.* ¶ 88.)

3. The Government's AWP Policies, Particularly As They Relate To Home Infusion Drugs, Raise A Genuine Issue Of Fact On Falsity.

Summary judgment on falsity is also inappropriate because the Government approved of, implemented, and maintained a system whereby healthcare providers were paid a premium on drugs, using compendia AWPs as the benchmark for payments, in order to cross-subsidize the admittedly inadequate fees paid to the providers for their labor and other medical services. The Government's cross-subsidization policy is nowhere more evident than in the arena of home infusion therapy, where the Subject Drugs were regularly used.

(a) Medicaid Policies For Infusion Drugs.

The record shows that state Medicaid programs clearly knew that the dispensing fees they paid to providers were woefully inadequate to cover the higher costs of home infusion therapy. (C. Br. at 10-18; AF ¶¶ 90-105, 110-113.) To compensate, the Medicaid programs officials *intentionally* paid a premium (the spread) to providers for the drugs they dispensed. (*Id.*) By paying what the Government misleadingly labels "mega-spreads" (which in actuality averaged only a few dollars per unit) on products like the Subject Drugs, the Medicaid programs were able to cross-subsidize the sub-par dispensing fees (often only a small fraction of the providers' actual labor and overhead costs) and thereby ensure equal access to care for Medicaid patients. (*Id.*)

This cross-subsidization policy is reflected in the states' reaction to the DOJ's 1999 effort to reduce Medicaid payment levels by implementing the "DOJ AWPs." Two-thirds of state Medicaid programs flatly rejected this effort, citing the higher cost to dispense IV medications and concerns about access to care. (C. Br. at 19-20.) Instead, those entities deliberately chose to continue paying providers based upon the allegedly "inflated" compendia AWPs. (*Id.*) Critically, even today, the vast majority of state Medicaid programs continue to use AWP as the payment benchmark, years after this Court has acknowledged that such payors had full

knowledge that AWP greatly exceeds actual market prices. (AF ¶ 123.)

Finally, a jury could infer a lack of "falsity" from CMS's deliberate failure to impose Federal Upper Limits ("FULs") on infusion drug payments, which would have prevented cross-subsidization by state Medicaid. CMS officials admitted that applicable law actually *required* that such FULs be implemented for the Subject Drugs, yet CMS refused to do so. (AF ¶¶ 114-122.) Other than testimony to the effect of "because they just weren't," no government witness has been able to articulate why the required FULs were never put in place. (*Id.*) Viewed in the light most favorable to Abbott, the obvious answer is that CMS deliberately chose to permit the widespread cross-subsidization at the state level to continue. This is certainly an issue the jury should decide.

(b) Medicare Policies For Infusion Drugs.

If anything, using the drug spread to cross-subsidize was even more critical in the Medicare world, because that program pays *no dispensing fee at all* to home healthcare providers for infusion therapies; rather, the providers only receive payment for the ingredient as a supply.[11] There can be no question that Medicare's cross-subsidization was intentional because, among other things, Congress was expressly told by CMS and providers in a 1993 hearing that CMS was paying and the providers were dependent upon the "spread" paid on drug products to make up for the lack of any payment for the providers' services. (AF ¶¶ 106-110.) Understanding the need for the spread, Congress went to great lengths to halt any proposals, like the "DOJ AWPs," that would radically reduce or eliminate the payment of drug spreads to providers without also

[11] Congress tried to create a home infusion benefit for Medicare beneficiaries, with the passage of the Medicare Catastrophic Coverage Act of 1988. Recognizing that home infusion had generally "not been covered by [] Medicare," CMS proposed to pay providers for the cost of the drugs administered plus a "per diem fee schedule amount of $45.44 to cover the total cost of pharmacy services, pharmacy supplies (including IV fluids), and pharmacy delivery service; nursing services and nursing supplies; and other patient equipment needs" for antibiotic therapy. 54 Fed. Reg. 46938, 46938-40 (Nov. 8, 1989). This fee schedule was never implemented, however, because the Act was quickly repealed, *see* Pub. L. 101-234, once again leaving home infusion providers to rely on the premium paid for drugs to keep their doors open and to maintain access to care for the elderly.

taking into account the need to implement service fees. (*See* C. Br. at 18-20.)

Perhaps the best evidence that Medicare knowingly and intentionally used AWP to cross-subsidize home infusion therapy (and thus that claims submitted based on AWP were not false) is the fact that *CMS is still doing so today*. With the Medicare Modernization Act of 2003, Congress enacted sweeping reform that, in general, reduced drug payments to the Average Sales Price ("ASP") plus a percentage while simultaneously increasing dispensing fees paid to providers (thus addressing the second half of the reimbursement issue in a way the DOJ AWPs did not). (CF ¶¶ 15-16.) Critically, however, *Congress exempted home infusion drugs from the ASP methodology and instead continues to pay for those drugs under Medicare based on the compendia AWPs* (even though CMS now receives ASP data from manufacturers). As former CMS Administrator Tom Scully noted, this was Congress' way to "freeze" reimbursement at "some level of cross-subsidy" for home healthcare providers.[12] (*Id.* ¶ 16.)

C. Genuine Issues Of Material Fact Preclude Summary Judgment On Causation.

There is also a genuine issue of material fact regarding whether Abbott "knowingly . . . cause[d] to be presented, a false or fraudulent claim" as required by 31 U.S.C. § 3729(a)(1). As an initial matter, the Government's motion as to Abbott is limited only to Medicaid claims, conceding that the jury must decide causation as to at least half of this case.

Moreover, Abbott was not the proximate cause of any allegedly false claims. (C. Br. at 34-36). Instead, the state Medicaid programs themselves were the proximate cause, since those programs devised and maintained reimbursement methodologies that based drug payments on the compendia AWPs, knowing full well that those AWPs were far higher than average market prices. (*Id.*; *see also* Part I.B.3 *supra*.) In addition, CMS's failure to set the required FUL for

[12] The cross-subsidization policies of the federal and state governments also raise a genuine issue of material fact as to Abbott's scienter and as to causation. (*See* C. Br. at 31-36.)

the Subject Drugs, thereby capping drug payments and preventing cross-subsidization, further breaks any possible causal link between Abbott's price reporting and the submission of "false" claims. (*See supra* Part I.B.3.b; C. Br. at 35-36; AF ¶¶ 114-122). Finally, CMS approved all state Medicaid plans, raising yet another factual dispute about CMS's approval of cross-subsidization, which bears on causation (and all other FCA elements as well.) (C. Br. at 34.)

D. Genuine Issues Of Material Fact Preclude Summary Judgment On Materiality And On Abbott's Affirmative Defenses.

For the reasons set forth in the defendants' common brief (at 33-36), there are disputed issues of fact surrounding the materiality element of the Government's FCA claims and also surrounding Abbott's affirmative defenses, making summary judgment inappropriate.

REPLY IN SUPPORT OF ABBOTT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

I. THE COURT SHOULD BAR DAMAGES FOR CLAIMS PAID AFTER VEN-A-CARE FILED COMPLAINTS NAMING THE DRUGS AT ISSUE.

A. Once Ven-A-Care's Complaint Was Filed In 1995, The Government Itself Was The Proximate Cause Of Any Allegedly Improper Payments.

Abbott's opening brief showed that (1) actual damages under the FCA cannot be recovered absent proof that the damages were *caused* by a false claim; (2) FCA causation is defined by reference to common-law tort causation concepts; (3) one such concept is that a party cannot recover "self-inflicted" damages; and (4) courts and commentators have concluded that the Government cannot recover actual FCA damages that it elects to suffer. (Mem. at 22-24.) The Government ignores Abbott's cases and argument entirely, and instead calls this issue "nothing more than" an allegedly improper mitigation-of-damages defense. (G. Def. Br. at 36.) That is wrong.

Mitigation of damages is the "principle requiring a plaintiff, after an injury or breach of contract, to make reasonable efforts to alleviate the effects of the injury or breach." BLACK'S

LAW DICTIONARY 1093 (9th ed. 2009). By contrast, where the "question [is] whether the damages [Plaintiff seeks] were *caused* by the conduct of which [it] complain[s]," the "doctrine of mitigation of damages is completely inapposite." *Fleet Nat'l Bank v. Anchor Media Television, Inc.*, 45 F.3d 546, 561 (1st Cir. 1995) (emphasis added). Here, Abbott's argument is not that the Government failed to reduce damages from an injury; it is that the Government *caused* its own purported injury in the first instance.[13] As the Government failed to dispute the actual damages causation argument made by Abbott, any opposition is waived. *See Joyce v. John Hancock Fin. Servs., Inc.*, 462 F. Supp. 2d 192, 212 (D. Mass. 2006) ("[Plaintiff] did not address [defendant's argument] in its memorandum of opposition and cross-motion for summary judgment. Consequently, the Court deems this argument waived and grants summary judgment….").

In any event, as shown in Abbott's brief, all of the Government's post-complaint actual damages must fail for lack of causation because, at least from the time of filing forward, there can be no dispute that the Government had detailed knowledge about the allegedly false claims and yet continued to pay them anyway – breaking any possible causal connection to Abbott. (Mem. at 25.) Although the Government states that it had only "limited knowledge gleaned from the relator's complaint and disclosure statement," (G. Def. Br. at 36), the record demonstrates that the Government in fact had extensive knowledge in and before 1995 about alleged AWP fraud – including specific knowledge through its own studies that the Subject Drugs at issue in this case were sold in the marketplace at discounts of 75% - 90% off of AWP. (*See* Part I.B.2 *supra*; *see also* C. Br. at 2; Dkt. No. 6183.)

[13] The Government also cites *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908 (4th Cir. 2003) and *United States v. Salti*, No. 1:96CV1065 (N.D. Ohio Feb. 2, 2000), both of which are wholly inapposite. *Harrison* rejected a challenge to the *materiality* of a false statement, while *Salti* found that a defendant's intent to defraud was not negated by the knowledge of undercover criminal investigators. These cases do not address damages causation, let alone hold that the Government may manufacture treble damages for itself by paying claims it believes to be false even as it prepares a lawsuit based on those very claims.

Moreover, even giving the Government tremendous leeway to investigate Ven-A-Care's allegations before acting, it had no excuse for continuing to pay the allegedly false claims after January 1, 1996 – over six months later, and three times the "investigatory" period deemed appropriate by Congress in the "vast majority" of FCA cases.[14] (*See* Mem. at 28-30.) At a minimum, the Court should cut off damages after such a reasonable period of time. *Cf. Rudsten v. Reynolds*, No. 80-0764, 1982 WL 1306, at *2-3 (D. Mass. Mar. 17, 1982) (limiting damages in securities fraud case to "a reasonable period of time after [Plaintiff's] learning of the alleged misrepresentation") (citing *Mitchell v. Tex. Gulf Sulphur Co.*, 446 F.2d 90, 105 (10th Cir. 1971)).

B. The Government's Due Process Violations Also Preclude Damages.

The record plainly shows that the Government abused the FCA's seal provision in order to gain tactical advantage, depriving Abbott of due process. (Mem. at 25-33.) Both the structure and legislative history of the FCA teach that the seal provision is not intended to allow delay for the purpose of one-sided discovery, and that the Government is not permitted to "unnecessarily delay lifting of the seal from the civil complaint or processing of the *qui tam* litigation," S. Rep. No. 99-345, at 25 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5290. Flouting the law, the Government: (1) took *65 times* longer to unseal this case than the 60-day period deemed "adequate" by Congress "in the vast majority" of cases; (2) made material misrepresentations in its *ex parte* briefs seeking repeated extensions of the seal period; and (3) sought extensions of the seal period for improper tactical reasons, such as taking one-sided discovery, retaining experts, creating litigation support structures, and pursuing settlement. (Mem. at 27-30.) Even as it

[14] Indeed, by early 1996, the Government's motions to extend the seal plainly demonstrated that the Government fully understood the factual and legal basis of Ven-A-Care's claims, and indeed had transitioned to full-litigation mode by no later than January 23, 1996, when the Attorney General authorized the issuance of civil investigative demands on Abbott. (SOF ¶¶ 62-64.) By May 1997, the Government was actively seeking to have *states* "advocate the recovery of that state's losses from the fraud scheme set forth in the Amended Complaint," unmistakably demonstrating that the Government had investigated the complaint and believed that the allegations were accurate. (*Id.* ¶ 65.)

engineered this incredible delay, the Government did nothing to preserve its own evidence, allowing critical materials to be lost and memories to fade, all to the undeniable prejudice of Abbott. (*Id.* at 31.)

Yet again, the Government responds by ignoring the case law cited by Abbott. (*See* G. Def. Br. at 41-44.) Instead, it relies upon a single, unpublished opinion – *United States ex rel. Sarmont v. Target Corp.*, 2003 WL 22389119 (N.D. Ill. Oct. 20, 2003) – in which a due process challenge to an FCA case delayed for 9½ years was rejected. That reliance is sorely misplaced.

First, the *Sarmont* court found that the majority of the delay, seven years, was due to the Government's "good cause showing" that it needed time to complete a *criminal* investigation[15] of the defendant. *Id.* at *4-6. Moreover, the defendant made no challenge to the "good cause" finding other than to point out the length of the delay, and the Court found no reason to revisit the transferor court's findings. *Id.* at *6. Here, by contrast, Abbott has shown that there was no pending criminal investigation to justify "good cause," the Government's *ex parte* brief misstated the legislative history on what "good cause" requires, and the Government's extension motions sought repeated delays for plainly improper tactical purposes. (Mem. at 29-30.) The Government does not and cannot deny any of these facts, which alone makes *Sarmont* inapposite.

Second, the *Sarmont* court noted that the delay was within what the court (apparently incorrectly) regarded as the FCA's statute of limitations,[16] whereas here the Government kept this matter under seal far beyond *both* the FCA's 3 and 6 year statutes of limitation, and even beyond the 10-year statute of repose. (Mem. at 28.)

Finally, the prejudice argument raised and rejected in *Sarmont* was that the *defendant*

[15] Notably, a pending criminal investigation is the only specific example of "good cause" cited in the FCA's legislative history. (*See* Mem. at 28 n.17.)

[16] The Court stated that the delay fell within the "ten year statute of limitations." *Id.* at *7. The FCA actually contains a *six-year* statute of limitations, an alternative 3-year statute of limitations, running from the time of discovery, and an ultimate 10-year statute of repose. *See* 31 U.S.C. § 3731(b); Mem. at 28.

might have destroyed exculpatory evidence in *its own files*, and that its *own* former employees might not be able to offer exculpatory testimony. 2003 WL 22389119, at *7. There was no challenge to the *Government's* failure to maintain evidence; rather, the potentially missing evidence was within the defendant's control, and the loss was speculative. *Id.*

In this case, Abbott has shown that the *Government* allowed evidence that was in *its* possession to be lost, prejudicing Abbott's defense. (Mem. at 31.) Although the Government claims that Abbott had informal notice and could have "prepar[ed] its defenses" (G. Def. Br. at 43), it does not deny that Abbott had no ability to demand evidence from the Government without access to civil discovery – access which Abbott was denied due to the extended seal period. Moreover, Abbott has identified specific documents that the Government has destroyed, and has deposed many Government witnesses who claim memory loss. (Mem. at 30-31; Dkt. No. 6097 at 10-18.) Abbott was prejudiced here, and this due process violation warrants a remedy.

II. THE HOME INFUSION CLAIMS DO NOT RELATE BACK TO VEN-A-CARE'S ORIGINAL COMPLAINT

Abbott has shown that the Government's newly-added claims relating to Abbott's former Home Infusion Services business are fundamentally different from those asserted by Ven-A-Care, rest on a separate legal basis, and therefore cannot relate back to the original 1995 complaint. (Mem. at 33-38.) The Government waves its hand at this issue, asserting that recent FCA amendments in the Fraud Enforcement and Recovery Act of 2009 ("FERA") resolve any relation-back problems. (G. Def. Br. at 27-29.) This is wrong for two reasons.

First, FERA's amendments do not apply retroactively to revive time-barred claims. (*See* C. Br. at 43-45.) *Second*, FERA did not undermine the authorities set forth in Abbott's opening brief. The plain text of the relevant amendment merely incorporates the Rule 15(c) standard, permitting relation-back only "to the extent that the claim of the Government arises out of the

conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person." 31 U.S.C. § 3731(c); *compare* Fed. R. Civ. P. 15(c)(1)(B) (setting forth identical "conduct, transaction, or occurrence" test). This is no accident. According to one of FERA's authors, the purpose of this amendment was to overrule *United States v. Baylor University Medical Center*, 469 F.3d 263 (2d Cir. 2006), by "clarif[ying] that the Government's complaint in intervention or amended complaint will relate back to the date of the original qui tam complaint so long as the conditions of Federal Rule of Civil Procedure 15(c)(2) [*sic*][17] otherwise are met." 155 Cong. Rec. E1287, 1295, 1299 (daily ed. June 3, 2009) (stmt. of Rep. Berman).

Abbott's Home Infusion argument relied on Rule 15(c), not *Baylor*, so nothing is changed by the new § 3731(c). Relation-back must still be denied because the Home Infusion claims do not arise out of the same "conduct, transaction, or occurrence set forth" in Ven-A-Care's complaint. (*See* Mem. at 33-37.) Indeed, the Government only makes one oblique reference to Rule 15(c), stating in a footnote that the Home Infusion allegations relate back because they "involve the submission of claims for the Subject Drugs that were at issue in relator's original complaint." (G. Abt. Br. at 31 n.22.) But merely saying that allegations are "related" in some "broad scheme" is insufficient to allow relation back where, as here, both the factual basis and the legal theory of liability for the Government's Home Infusion claims are markedly different from the indirect, pricing-related violations alleged by Ven-A-Care. (*See* Mem. at 35-37 & n.21.) The Home Infusion claims should be dismissed as untimely.

CONCLUSION

For the reasons above and in the associated briefing, Abbott's motion for partial summary judgment should be granted, and the Government's cross-motion denied in its entirety.

[17] At the time *Baylor* was decided, Rule 15(c)(2) was the rule setting forth the same "conduct, transaction, or occurrence" test. Rule 15(c)(2) has since been renumbered as Rule 15(c)(1)(B).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David S. Torborg, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S MEMORANDUM IN OPPOSITION TO THE UNITED STATES' MOTION FOR PARTIAL SUMMARY JUDGMENT, AND REPLY IN SUPPORT OF ABBOTT'S MOTION FOR PARTIAL SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 28th day of August, 2009.

/s/ David S. Torborg
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